

WHAT IS CLAIMED IS:

1. A stable pharmaceutical composition comprising about 1 wt. % to about 80 wt. % of an ACE inhibitor or a pharmaceutical acceptable salt thereof, about 1 wt. % to about 70 wt. % of an alkali or alkaline earth metal carbonate, and about 1 wt. % to about 80 wt. % of hydroxypropyl cellulose, wherein the ACE inhibitor is selected from the group consisting of quinapril, enalapril, spirapril, ramipril, perindopril, indolapril, lisinopril, alacepril, trandolapril, benazapril, libenzapril, delapril, cilazapril and combinations thereof; wherein the formation of an internal cyclization product, and/or ester hydrolysis product, and/or oxidation product, has been reduced or eliminated, and the weight percents are based on the total weight of the pharmaceutical composition.
2. The composition according to Claim 1, wherein the ACE inhibitor is selected from the group consisting of quinapril, enalapril and spirapril.
3. The composition according to Claim 1, wherein the ACE inhibitor is quinapril hydrochloride.
4. The composition according to Claim 1, wherein the amount of the ACE inhibitor or a pharmaceutical acceptable salt thereof is from about 5 wt. % to about 50 wt. %, based on the total weight of the pharmaceutical composition.
5. The composition according to Claim 4, wherein the amount of the ACE inhibitor or a pharmaceutical acceptable salt thereof is from about 10 wt. % to about 15 wt. %, based on the total weight of the pharmaceutical composition.
6. The composition according to Claim 1, wherein the alkali metal is selected from the group consisting of lithium, sodium, potassium, rubidium, cesium and francium.
7. The composition according to Claim 1, wherein the alkaline earth metal is selected from the group consisting of magnesium, calcium, barium, strontium and radium.
8. The composition according to Claim 7, wherein the alkaline earth metal is magnesium.

9. The composition according to Claim 1, wherein the amount of the alkali or alkaline earth metal carbonate is from about 10 wt. % to about 60 wt. %, based on the total weight of the pharmaceutical composition.
10. The composition according to Claim 9, wherein the amount of the alkali or alkaline earth metal carbonate is from about 45 wt. % to about 55 wt. %, based on the total weight of the pharmaceutical composition.
11. The composition according to Claim 1, wherein the hydroxypropyl cellulose has a molecular weight of from about 50,000 to about 1,250,000.
12. The composition according to Claim 11 wherein the hydroxypropyl cellulose has a molecular weight of from about 80,000 to about 1,150,000.
13. The composition according to Claim 1, wherein the hydroxypropyl cellulose is a low-substituted hydroxypropyl cellulose.
14. The composition according to Claim 1, wherein the low-substituted hydroxypropyl cellulose when dried at 105 °C for 1 hour contains 5-16% of hydroxypropoxy groups.
15. The composition according to Claim 14, wherein the low-substituted hydroxypropyl cellulose when dried at 105 °C for 1 hour contains 10-13% of hydroxypropoxy groups.
16. The composition according to Claim 13, wherein the low-substituted hydroxypropyl cellulose is selected from the group consisting of: LH-11 having a hydroxypropoxy content of 11% and an average particle size of 50 microns; LH-21 having a hydroxypropoxy content of 11% and an average particle size of 40 microns; LH-31 having a hydroxypropoxy content of 11%, and an average particle size of 25 microns; LH-22 having a hydroxypropoxy content of 8%, and an average particle size of 40 microns; LH-32 having a hydroxypropoxy content of 8%, and an average particle size of 25 microns; LH-20 having a hydroxypropoxy content of 13%, and an average particle size of 40 microns; and LH-30 having a hydroxypropoxy content of 13%, and an average particle size of 25 microns.
17. The composition according to Claim 16, wherein the L-HPC is LH-21 or LH-11.
18. The composition according to Claim 1, wherein the hydroxypropyl cellulose is present in an amount of from about 10 wt. % to about 50 wt. %.

19. The composition according to Claim 18, wherein the hydroxypropyl cellulose is present in an amount of from about 30 wt. % to about 40 wt. %.
20. The composition according to Claim 1, which is in the form selected from the group consisting of a tablet, granules, bar, block, disc, capsule, caplet and powder.
21. A method of preparing a stable pharmaceutical composition comprising about 1 wt. % to about 80 wt. % of an ACE inhibitor or a pharmaceutical acceptable salt thereof, about 1 wt. % to about 70 wt. % of an alkali or alkaline earth metal carbonate, and about 1 wt. % to about 80 wt. % of hydroxypropyl cellulose, wherein the ACE inhibitor is selected from the group consisting of quinapril, enalapril, spirapril, ramipril, perindopril, indolapril, lisinopril, alacepril,trandolapril, benazapril, libenzapril, delapril, cilazapril and combinations thereof; wherein the formation of an internal cyclization product, and/or ester hydrolysis product, and/or oxidation product, has been reduced or eliminated, and the weight percents are based on the total weight of the pharmaceutical composition, said method comprising:
- (a) mixing the ACE inhibitor or a pharmaceutical acceptable salt thereof, an alkali or alkaline earth metal carbonate, hydroxypropyl cellulose, and optionally one or more excipients, to form a premix;
  - (b) adding a solvent, and optionally one or more excipients, to the premix formed in Step (a) to form a wet granulation;
  - (c) drying the wet granulation to form granules, and optionally milling the granules; and
  - (d) optionally mixing one or more excipients with the granules to form a pharmaceutical composition.